IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

STEPHANIE FRATER, Individually and On Behalf Of All Others Similarly Situated, Plaintiffs, v. HEMISPHERX BIOPHARMA, INC., WILLIAM A. CARTER, DAVID STRAYER, and WAYNE PAMBIANCHI, Defendants.	2:12-cv-07152-WY

MEMORANDUM

YOHN, J. January 23, 2014

This is a consolidated class action in which plaintiffs are shareholders or former shareholders of Hemispherx Biopharma, Inc. ("Hemispherx"). Plaintiffs claim securities fraud under § 10(b) of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5 thereunder against Hemispherx; its President and Chairman of the Board Dr. William A. Carter; its Medical Director and Chief Medical Officer David Strayer; and its Senior Advisor Wayne Pambianchi. They further claim Hemispherx and Carter violated § 20(a) of the Exchange Act. The plaintiffs purport to represent all persons other than defendants who purchased or acquired Hemispherx common stock on the open market between March 14, 2012 and December 20, 2012, inclusive.

The subject of this litigation is the regulatory approval process of Ampligen, Hemispherx's flagship drug which the Food and Drug Administration ("FDA") had not yet approved for market as of the class period. The consolidated amended complaint ("complaint") alleges that, during the class period, Hemispherx and its senior officials made numerous public statements that concealed and/or misrepresented information indicating Hemispherx was not likely to succeed in obtaining Ampligen approval.

Before the court is the defendants' motion to dismiss, which contends plaintiffs have failed to state a claim under § 10(b) and Rule 10b-5. The defendants further contend that, to the extent the plaintiffs have failed to state a claim under § 10(b), they have also failed to state a claim under § 20(a).

Drawing all inferences in the plaintiffs' favor, one may reasonably infer from the complaint that the defendants made statements that were misleading and/or omitted information necessary to avoid their being misleading, as well as strongly infer the defendants knew this or were reckless if they did not know this. The inference of scienter emerges from numerous, detailed allegations of specific information known to the defendants but not disclosed. The allegations are thus sufficient to state a claim, and the defendants' motion will be denied.

I. Background[1]

[1] A motion to dismiss under Rule 12(b)(6) tests the legal sufficiency of the complaint. *See* Fed. R. Civ. P. 12(b)(6). In evaluating a motion to dismiss, a court is to give full credit to the facts pled by plaintiffs, including plausible inferences made from facts pled with particularity. *Santiago v. Warminster Twp.*, 629 F.3d 121, 130 (3d Cir. 2010) (citing *Ashcroft v. Iqbal*, 556 U.S. 662 (2009)). In this case, the defendants urge the court to also consider the contents of 43 exhibits attached to its brief under the doctrine of judicial notice. *See Institutional Investors Group v. Avaya*, 564 F.3d 242, 252 (3d Cir. 2009). Of these 43 exhibits, I will take judicial notice of Exhibit 27, containing the FDA's minutes from its June 8, 2012 meeting with Hemispherx, for reasons discussed later in this opinion. Of the rest, a substantial portion (Ex. 1-6; 17-26; 30-35; 41-43) are documents which plaintiffs rely upon but faithfully characterize, such that the exhibits clutter the record without aiding in the evaluation of whether the pled facts state a claim on which relief can be granted. The remainder (Ex. 7-16; 28-29; 36; 38; 40) are non-official documents the complaint does not rely upon and, in most cases, to which the complaint does not even refer. Should the defendants believe that these documents provide credible evidence tending to undermine plaintiffs' claims, they are more than free to present them in a motion for summary judgment or to a factfinder at the appropriate time. Given that a

A. The FDA New Drug Approval Process

Under 21 U.S.C. § 355, companies may market a pharmaceutical product in the United States only after submitting a new drug application ("NDA") to the FDA and receiving the FDA's approval. *See* 21 U.S.C. § 355. The FDA may approve a drug for market only where there is (a) sufficient information to determine the drug is safe to use as proposed, and (b) substantial evidence the drug will have the effect it is purported to have when used as proposed. § 355(d)(4)-(5).

Where a company seeks to sponsor a previously untested drug for FDA approval, the company is responsible for undertaking clinical investigation to demonstrate the drug's safety and effectiveness. *See* 21 C.F.R. § 312.21. This includes the design, conduct, and analysis of clinical trials. *See id*. When a sponsor believes that clinical investigation has produced the substantial evidence of safety and efficacy required by § 355(d)(4)-(5), it may then file an NDA with the FDA based on that evidence. Even then, the FDA will only review the NDA if it is sufficiently complete to permit the FDA to conduct a substantive review on the merits of the application. If the FDA chooses to conduct the review, under the Prescription Drug User Fee Act ("PDUFA"), it has 180 days from the date of a filing to either approve the drug or send the sponsor a confidential statement of the FDA's reasons for denying the application. This confidential statement is known as a Complete Response Letter ("CRL"). If the sponsor receives a CRL, it may resubmit the NDA at a later date.[2]

Prior to the 180-day deadline for approving the drug candidate, the FDA may elect to convene an advisory panel to make technical recommendations related to an application and/or

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motion under Rule 12(b)(6) tests the *legal* sufficiency of the complaint, however, the competing offerings of the defendant are impertinent in evaluating the plaintiffs' claims at this stage. Accordingly, this background statement reflects, and my analysis considers, the plaintiffs' allegations as well as the defendants' Exhibit 27.

[2] A resubmission of an NDA is sometimes known as a "complete response," and this is reflected in communications between the FDA and Hemispherx.

to publicly comment on any controversies relating to the drug candidate. Such an advisory committee meeting is the only occasion on which the FDA is permitted to publicly communicate concerns about an NDA.

B. Hemispherx

Hemispherx is a Philadelphia-based, development-stage pharmaceutical company with one drug that generates significant revenues: Ampligen. Ampligen was developed by Carter in the 1970s while a university researcher, and, since at least 1988, Hemispherx has pursued FDA approval of Ampligen as a treatment for chronic fatigue syndrome ("CFS").

Hemispherx is a public company and its stock is traded on a national exchange.

C. Ampligen Trials

In 1990 and 1991, Hemispherx conducted a placebo-controlled, proof-of-concept trial for Ampligen known as AMP 502. With AMP 502, Hemispherx aimed to demonstrate Ampligen improved participants' quality-of-life and physical endurance. The trial, however, deviated from its pre-specified protocol in at least six ways: (1) failing to determine a statistical analysis plan until after the study was unblinded; (2) switching from a 48-week trial to a 24-week trial mid-stream, without proof that the switch did not violate the study blind; (3) including only 92 participants in the trial instead of 100 participants as specified; (4) excluding an additional seven participants in evaluating the data from the endurance test; (5) using some participants' best performances and others' worst performances when evaluating the quality-of-life test; and (6) failing to demonstrate that there were no participants in the trial who the trial protocol required to be excluded. According to the complaint, Hemispherx was aware of these flaws and the possibility that they compromised the study's statistic and scientific validity.

In 1997, Hemispherx began a second placebo-controlled clinical trial of Ampligen, this one known as AMP 516. AMP 516 was designed as a 40-week trial with twin primary goals of showing Ampligen improved patients' quality-of-life and physical endurance. Like AMP 502, the AMP 516 trial deviated from its protocol, including: (1) changes to trial parameters over the course of the study; (2) failing to establish controls that would avoid reporting false positive results; (3) failing to calculate results in accordance with the trial protocol; (4) failure of the study blind; and (5) abandoning the statistical analysis technique specified in the protocol when it failed to demonstrate Ampligen improved participants' endurance. Meanwhile, under any analysis, AMP 516 failed to demonstrate Ampligen improved participants' quality-of-life. Some participants in AMP 516 were included in a 24-week continuation study known as AMP 516C, in which participants received Ampligen even if they had received placebos in AMP 516. A comparison between the results for patients who received placebos in AMP 516 but Ampligen in AMP 516C and the results for patients who received Ampligen in AMP 516 tended to show Ampligen was ineffective.

D. The First Ampligen Application and Hemispherx Response

In October 2007, based on the findings of AMP 502 and AMP 516, Hemispherx submitted the first Ampligen NDA. The FDA refused to consider the application, however, citing clerical errors and/or facial discrepancies in Hemispherx's report. In April 2008, Hemispherx resubmitted the initial Ampligen NDA, and this time the FDA accepted it for review.

In November 2009,[3] after a period of review, the FDA sent Hemispherx a CRL explaining it would not be approving Ampligen. On December 1, 2009, Hemispherx issued a press release purporting to represent the explanation the FDA had given for denying the

[3] It is not clear from the complaint why the FDA took longer than 180 days to respond to the resubmitted Ampligen NDA. According to the complaint, however, Hemispherx and/or its senior agents have represented that the delay was not related to NDA deficiencies.

application. According to that press release, the CRL communicated the FDA determined "the two primary clinical studies submitted with the NDA did not provide credible evidence of efficacy of Ampligen and recommend[ed] at least one additional clinical study which shows a convincing effect and confirms safety in the target population."

Despite Hemispherx's awareness (1) of methodological problems with AMP 502 and AMP 516, (2) the FDA's determination that AMP 502 and AMP 516 did not produce credible evidence of Ampligen's efficacy, and (3) the FDA's specific recommendation in the CRL to pursue an additional clinical study, Hemispherx focused its post-CRL attention on reanalyzing the AMP 502 and AMP 516 trial results. These efforts first turned on finding a "biomarker" for Chronic Fatigue Syndrome, so as to better facilitate determining whether AMP 502 and AMP 516 participants actually suffered from Chronic Fatigue Syndrome rather than an alternative source of a similar set of symptoms. As of January 2012, however, multiple attempts by Hemispherx to find a biomarker for CFS had failed, such that biomarker-based assessment of Ampligen's effect in AMP 502 and AMP 516 was not an option.

By this point, Hemispherx allegedly lacked sufficient resources to conduct a new clinical trial. Instead, its options apparently limited, Hemispherx continued to attempt to demonstrate the safety and efficacy of Ampligen through reanalysis of the AMP 516 data. On March 14, 2012—the first day of the class period—Hemispherx published an article written by Hemispherx executives including Carter and Strayer in an open-source, online trade journal called PLoS One. Although advertised as a peer-reviewed journal, PLoS One publishes over 2/3 of submissions and typically accepts a publication fee of over $1,000 from authors. Addressing AMP 516's empirical bonafides, the article stated "the design of the study, including endpoint, and the statistical method used to define efficacy were all reviewed by the FDA prior to receipt of FDA

authorization for the initiation of the study." Substantively, the PLoS One article put forth a new analysis of the AMP 516 data that concluded Ampligen yielded statistically significant benefits for a number of defined subgroups within the trial, as measured by both endurance and quality-of-life metrics. The new analysis also concluded these findings were further supported by the data from the AMP 516C continuation group.

The PLoS One article did not mention AMP 516's numerous departures from its protocol or the possibility they may have compromised the empirical validity of the trial's results. Nor did it address the fact that the results of the new analysis differed from the results of the previous AMP 516 analysis, which, as the FDA communicated to Hemispherx in its 2009 CRL, did not demonstrate that Ampligen was effective. Moreover, plaintiffs allege the analysis contained in the PLoS One article was the product of cherry-picking subgroup-specific data, such that its conclusions were the product of pro-Ampligen manipulation. The PLoS One article did not refer to and did not discuss these alleged analytic defects, either.

On March 19, 2012, Hemispherx issued a press release trumpeting the article's findings. In it, Hemispherx emphasized that PLoS One was "peer-reviewed."

E. The Second Ampligen Application

March 14, 2012—the first day of the class period and the day the PloS One article was publishedalso saw Hemispherx announce in an SEC filing that it was planning to resubmit the Ampligen NDA. According to the announcement, Hemispherx "believe[d] that continued efforts to understand existing data and to advance the development of new data and information, will ultimately support a refiling of the NDA." Thus began Hemispherx's second appeal to the FDA for approval of Ampligen. Because Hemispherx had not developed new data since AMP 516, the

decision to proceed with a near-term refiling meant that, in practice, the viability of application would depend on Hemispherx's reanalysis of AMP 502 or AMP 516.

Approximately one week later, on March 22, 2012, Carter and Strayer hosted a conference call for investors regarding the Ampligen NDA. Discussing the decision to proceed with resubmission, Strayer stated there was "no need for a CFS biomarker to get Ampligen approval." Carter, meanwhile, expressed confidence that Hemispherx's new analysis of AMP 516 would be sufficient to answer the concerns the FDA expressed in the CRL. When an investor challenged Carter on the basis that the FDA had urged Hemispherx to perform a new trial, Carter referred to an intervening statute amending the PDUFA process—The Food and Drug Administration Safety and Innovation Act ("FDASIA"). According to Carter, FDASIA "expanded the basis for accelerated approval under the conditional approval process." Notwithstanding Carter's characterizations, the complaint alleges FDASIA adjusted the timetable of the new drug review process for a category of drugs that did not include Ampligen, and, as to the investor's question, had no bearing whatsoever on the quantum of evidence required to demonstrate new drug effectiveness.[4]

On June 8, 2012, Carter and Strayer met with FDA officials to discuss Hemispherx's planned approach to the NDA. According to FDA minutes of that meeting,[5] FDA officials told Hemispherx:

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[4] This interpretation by the plaintiffs is further supported by the FDA's statement to Hemispherx in a private meeting with Carter and Strayer on June 8, 2012, *infra*, that "The standards for approval require the same evidence of efficacy and safety, regardless of approval pathway."

[5] This communication is the defendants' Exhibit 27, which defendants ask I take judicial notice of. Although the complaint does not explicitly refer to this document, it does appear to be the basis of the complaint's allegation of the FDA's warning to Hemispherx on June 8. Moreover, as the defendants note, it is a document of a public agency. While the plaintiffs and defendants' disagree on whether doctrine of judicial notice should apply given that the FDA's minutes are confidential, I fail to see what injury could come to plaintiffs from a document tending to show that the FDA directly noticed the defendants that their request for additional study from the CRL remained intact, that the PDUFA review process applied the same standard of scrutiny as prior to FDASIA, and that it would be

> You [Hemispherx] propose new post-hoc analyses of data from Trial 516 and a post-marketing trial (AMP-520) to support approval. It would be unusual for this type of data to provide adequate evidence of efficacy. However, the adequacy of the data will ultimately be a review issue, and it is reasonable for you to submit a complete response. This complete response needs to address all of the issues defined in the complete response letter dated November 25, 2009. As Ampligen is a new molecular entity, we anticipate that the data submitted in your NDA would be presented at a public Advisory Committee meeting... The standards for approval require the same evidence of efficacy and safety, regardless of approval pathway.

On July 11, 2012, Hemispherx issued a press release announcing the June 8 meeting and stating what it purported to believe were the key takeaways. The press release announced that, as to Hemispherx's plan to base its resubmission on the new analysis of AMP 516, the FDA communicated that whether new analysis of AMP 516 "provide[d] adequate evidence of Ampligen's efficacy in treating CFS [would] ultimately be a review issue." The press release did not mention the FDA's immediately preceding statement that it would be unusual for such an approach to demonstrate adequate evidence of efficacy.

On August 1, 2012, Hemispherx announced it had resubmitted the Ampligen NDA. Discussing the resubmission, the press release stated "The FDA has agreed to accept, for review, further analyses of the data from Hemispherx's AMP 516 Phase III clinical trial and other Ampligen trials (AMP 502 and AMP 516C) in lieu of the additional confirmatory Phase III study originally called for in the Agency's CRL." Discussing the statutory updates to the PDUFA process, the release stated "Hemispherx believes that the data and analysis provided in its complete response may be relevant to the potential for approval of Ampligen under this expanded statutory authority. There can be no assurance, however, how the FDA will implement the new FDASIA provisions." Finally, referring to the publication of the AMP 516 reanalysis in PLoS One article, the press release described the new evaluation as "a peer reviewed analysis of

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unusual for adequate evidence of efficacy to be shown by the kind of post-hoc reanalysis upon which Hemispherx intended to base its NDA. Accordingly, I assent to defendants' request, and consider Exhibit 27.

data from the AMP 516 Trial." According to the plaintiffs, the FDA never withdrew its request for an additional trial.

Between August 1, 2012 and the end of the class period, Hemispherx several times more claimed (a) the FDA had expressed favorability to resubmission based on reanalysis of AMP 516 rather than new trial data, and (b) the statutory amendments to the PDUFA process were relevant to the timetable and/or likelihood the FDA would approve Hemispherx's application.

First, on August 8, 2012, Hemispherx released a quarterly report which said:

> We believe the key points from the meeting [with the FDA] to be undertaken included . . . [that] the FDA agreed to accept, for review, in Hemispherx's complete response new analyses of data from the AMP 516 Trial. Whether these data provide adequate evidence of efficacy will ultimately be a review issue, and there can be no assurance the FDA will conclude the data are adequate to support approval of the Ampligen NDA.

Second, on September 11, 2012, Pambianchi made a presentation to an investor conference on behalf of Hemispherx, at Carter's Request. As to the June 8 meeting with the FDA, Pambianchi stated:

> [The FDA] shared with Hemispherx its intent to withdraw the request that was in the complete response letter the company received in 2009. Part of that complete response letter requested that the company conduct another study. In lieu of another study, now the FDA is examining data in a new way and newly submitted data, some of which is in the publications that have been authored by Hemispherx in the last year or so. . . . They decided to accept in lieu of another study an examination of data in a new department within the FDA.

As to FDASIA and the NDA approval process, Pambianchi stated:

> "I mentioned earlier this new law that President Obama signed and I think that sets the stage for a favorable outcome at the PDUFA date, but once again, we can't make that prediction with 100 percent certainty.

Third, on September 13, 2012, Carter gave an interview to a trade publication in which he stated "we believe we have met the new statutory requirements which would logically lead to an acceleration of an approval."

Fourth, on September 24, 2012, Hemispherx issued a press release that stated:

> The company believes that the FDA's recently expanded statutory authority under the Food and Drug Administration Safety and Innovation Act may be relevant to the potential for approval of Ampligen, although there can be no assurance how the FDA will implement the new FDASIA provisions.

Fifth, on November 2, 2012, Hemispherx issued a quarterly report in which it announced it had received the FDA's minutes of the June 8 meeting. The report said:

> The company believes the key points from the meeting to be undertaken by the Company in conjunction with its complete response include the following: The FDA agreed to accept, for review, in Hemispherx's complete response new analyses of data from the AMP 516 Trial. Whether these data provide adequate evidence of efficacy will ultimately be a review issue, and there can be no assurance the FDA will conclude the data are adequate to support approval of the Ampligen NDA.

At no point in the class period did Hemispherx notify the public of the procedural and empirical problems with its AMP 516 reanalysis; nor did it publicly disclose the FDA's statement that reanalysis of previously submitted data would not ordinarily support approval; nor did it explain that FDASIA dealt only with timing of review and not standards of review, despite the FDA's statement about approval pathways at the June 8 meeting.

F. Hemispherx Stock

Concurrent with pursuing the resubmission of the Ampligen NDA in mid-late 2012, Hemispherx, which allegedly lacked resources to pursue a new clinical trial of Ampligen, took to the capital markets to raise cash for the firm. On July 23, 2012, just one week before Hemispherx's press release announcing the NDA resubmission, Hemispherx signed an equity distribution agreement with an investment company. Hemispherx sold 29.5 million shares of stock between July 23 and the end of the class period on December 18, generating $23 million in proceeds to Hemispherx based on then-existing prices. Carter persuaded Hemispherx's Board of Directors that these stock sales triggered a change-of-control provision in his contract and that of

Hemispherx's general counsel; as a result, each personally received a bonus in the form of 5% of the $23 million proceeds.

G. The FDA Advisory Committee and the Market Response

At some point after Hemispherx resubmitted the Ampligen NDA, the FDA elected to convene an advisory committee to discuss the Ampligen NDA. On December 18, the FDA published a briefing package on issues to be discussed at the advisory committee meeting, scheduled for two days later on December 20. With respect to AMP 502, the briefing package indicated it suffered from "multiple protocol violations." These included (1) improper removal of properly enrolled patients; (2) mid-study change in study design from 48 weeks to 24 weeks; (3) determination of the statistical analysis plan sixteen years after the study and significant modifications to that plan another five years later; (4) lack of demonstration that patients who were supposed to be excluded were in fact excluded; and (5) inconsistent use of data. With respect to AMP 516, the briefing package noted, among other things: (1) the FDA communicated to Hemispherx in June 2012 that it would be unusual for post-hoc analysis of previously submitted data to provide adequate evidence of efficacy; (2) the FDA had previously criticized Hemispherx's AMP 516 analysis as including patients whose performance improved but excluding patients whose performance deteriorated; (3) the statistical approach to analyzing AMP 516 had been manipulated to manufacture evidence of efficacy after the data was unblinded; (4) there was no meaningful evidence of efficacy when proper statistical analysis was employed; and (5) the AMP 516C data showed no statistical evidence of Ampligen's efficacy. The FDA briefing further noted (1) discrepancies in Hemispherx's safety data; (2) several prior warnings by the FDA to Hemispherx of the need to follow protocol and proper scientific and

statistical methodology; and (3) multiple previous denials by the FDA of Hemispherx's attempts to obtain an accelerated approval schedule for the Ampligen NDA.

When the advisory committee met two days later, FDA personnel explained that the purpose of the meeting was to facilitate a public discussion of the data underlying the Ampligen submission. The FDA then described in further detail the problems mentioned in the pre-meeting briefing package, including substantive issues underlying the Ampligen studies and the FDA's past dealings with Hemispherx. FDA clinical personnel again disputed that changes to the PDUFA included reductions in the quantum of evidence required for new drug approval, and they emphasized the FDA never waived its recommendation for an additional clinical trial of Ampligen as contained in the 2009 CRL. In view of multiple discrepancies between Hemispherx's data and its findings and multiple departures from protocol in the AMP 502 and AMP 516 studies, the FDA clinical personnel asked the Advisory Committee members to evaluate whether the resubmitted Ampligen NDA involved fraud or deception. At the conclusion of the meeting—after the close of the stock market on December 20, 2012—the Advisory Committee voted that the Ampligen NDA failed to include substantial evidence of Ampligen's efficacy or safety. Approximately six weeks later, on February 4, 2013, the FDA sent Hemispherx a CRL again denying the Ampligen NDA.

On December 19, 2012—the day after the FDA issued its briefing package—Hemispherx's share price dropped 43% in value to a close of $0.368 per share. Between the close of the markets on December 20 and the opening of the markets on December 21—during the interim of which the Advisory Committee held its meeting on the Ampligen NDA—Hemispherx shares dropped another 23% to a closing price of $0.280 per share. Between

December 21 and the time of the complaint, Hemispherx shares did not achieve a closing price above $0.30.

II. Standard of Review

A motion to dismiss under Rule 12(b)(6) tests the legal sufficiency of a complaint. Fed. R. Civ. P. 12(b)(6). In evaluating whether a complaint is sufficient, a court takes note of the elements the plaintiff must plead to state a claim and determines whether the plaintiff's well-pleaded factual allegations plausibly give rise to an entitlement for relief. *Santiago v. Warminster Twp.*, 629 F.3d 121, 130 (3d Cir. 2010) (citing *Ashcroft v. Iqbal*, 556 U.S. 662 (2009)). "[F]aced with a Rule 12(b)(6) motion to dismiss a § 10(b) action, courts must, as with any motion to dismiss for failure to plead a claim on which relief can be granted, accept all factual allegations in the complaint as true." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

Because this is a securities fraud case, it is not enough that, "under any reasonable reading of the complaint, plaintiff[s] may be entitled to relief." *Cf. Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008). Rather, the complaint must also comport with the specialized pleading requirements of the Private Securities Litigation Reform Act ("PSLRA"). *Institutional Investors Grp. v. Avaya, Inc.*, 564 F.3d 242, 252 (3d Cir. 2009). To satisfy the terms of the PSLRA, the complaint must "specify each allegedly misleading statement, why the statement was misleading, and, if an allegation is made on information and belief, all facts supporting that belief with particularity." *Id.* (construing 15 U.S.C. § 78u–4(b)(1)) (internal quotation omitted). The complaint must also, "with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u–4(b)(2). Under the PSLRA's "exacting" standard for pleading scienter, "a complaint will survive . . . only if a reasonable

person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 313, 324. The inquiry is "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Tellabs*, 551 U.S. at 323.

III. Discussion

A. § 10(b) and Rule 10b-5

To state a claim for securities fraud under § 10(b) and Rule 10b–5, a plaintiff must allege (1) a misstatement or omission of material fact, (2) with scienter, (3) in connection with the purchase or the sale of a security, (4) upon which the plaintiff reasonably relied, and (5) that the plaintiff's reliance was the proximate cause of their injury. *Avaya*, 564 F.3d at 251; *Winer Family Trust v. Queen*, 503 F.3d 319, 326 (2007). The defendants in this case do not dispute that the plaintiffs have pled statements by the defendants that were made in connection with transactions of Hemispherx stock, that the plaintiffs reasonably relied on these statements, or that this reliance caused them injury. Rather, the defendants contend the plaintiffs have failed to identify actionable misstatements or omissions of material facts, and that the complaint does not support the strong inference of scienter required by the PSLRA.

1. Actionable Misstatements or Omissions of Material Fact

a. Misstatements and/or Omissions

The defendants contend the complaint does not adequately support the proposition that their alleged statements regarding Ampligen and/or resubmission of the Ampligen NDA were false and/or misleading. In response, the plaintiffs point to numerous alleged statements which a factfinder could reasonably find to be false or misleading.

I agree with plaintiffs as to at least five types of statements referred to in the complaint.[6]

First, there are the defendants' statements characterizing the feedback Hemispherx received from the FDA at the June 8 meeting regarding its plan to base the Ampligen NDA resubmission on reanalysis of previously submitted data. According to these statements, the FDA told Hemispherx it could permissibly resubmit based on such information, although whether the information demonstrated efficacy and/or safety was ultimately an issue for review. However, in all statements referenced by the complaint, the defendants omitted the FDA's immediately preceding statement that it would be "unusual" for such reanalysis to provide sufficient evidence for approval. A reasonable person could have understood this to be a cautionary warning by the FDA that it was unlikely to be receptive to Hemispherx's planned approach. On this view, transmitting the latter part of the FDA's guidance but not the former would mislead an attentive investor by suggesting the FDA expressed greater receptivity to Hemispherx's approach to the Ampligen NDA resubmission than the FDA had expressed in fact.

Second, there are the defendants' statements that the FDA withdrew its request that Hemispherx include a new Ampligen clinical trial as part of a resubmitted NDA. According to this allegation in the complaint, which I must accept as true for this purpose, the FDA did not withdraw that request. If that is the case, then defendants' statements to the contrary were false.

Third, there are the defendants' statements claiming Hemispherx's analyses of AMP 502 and/or AMP 516, including the reanalysis of AMP 516 published by Hemispherx, Carter, and Strayer in PLoS One, demonstrated Ampligen's effectiveness. The complaint alleges—with support from the FDA's briefing package and the FDA's comments at the advisory committee meeting—that AMP 502, AMP 516, and AMP 516C were rife with methodological errors and

[6] Although I discuss these statements in groups for the sake of efficiency, I note that the complaint specifically identifies at least 13 allegedly misleading statements by defendants and, for each, identifies why the plaintiffs believe it to be misleading. *See Avaya*, 564 F.3d at 252; 15 U.S.C. § 78u–4(b)(1).

that their results only demonstrated Ampligen's efficacy with faulty statistical analysis. A factfinder could easily determine that announcements that Hemispherx's studies demonstrated Ampligen's effectiveness implied those studies' empirical validity and analytic soundness. To the extent that the cited conclusions were the product of statistically unsound analyses of empirically defective trials, statements lauding those conclusions would be misleading.

Fourth, there are the defendants' representations about external review related to the reanalysis contained in the PLoS One article. To this effect, while the PLoS One article stated the FDA reviewed and authorized all aspects of the AMP 516 study design, the AMP 516 study did not adhere to the trial protocol nor did it employ the statistical analysis it had discussed with the FDA. Meanwhile, Hemispherx statements described the PLoS One article as "peer-reviewed" notwithstanding that PLoS One's self-publish, fee-based, high-acceptance model is a substantial departure from the models used by other peer-reviewed journals. In each case, a factfinder could conclude the defendants misleadingly declared a greater level of external approval of Hemispherx's clinical and statistical methods than was in fact the case.

Fifth, there are the defendants' statements about the possibility of Ampligen benefitting from statutory updates to the new drug approval process. In context, these statements may fairly be read to say these updates (a) lowered the quantum of evidence supporting efficacy and/or safety that Hemispherx needed to present for the Ampligen NDA to be approved, and/or (b) created a viable path for placing the Ampligen NDA on an accelerated timetable. The complaint alleges that, actually, the updates to the drug approval process did not affect the quantum of evidence required for approval and that accelerated review was categorically unavailable for Ampligen. I must accept the plaintiffs' view at the motion to dismiss stage. Insofar as defendants

made statements to the contrary—which a fair reading of the statements suggests—then those statements were false.

b. Materiality

The defendants argue that, even if their statements were false and/or misleading, they were not material. The plaintiffs' allegations support a finding of materiality.

In short, the complaint alleges statements by the defendants which may fairly be seen to: (1) underplay FDA negative feedback on its approach to obtaining approval of Ampligen; (2) falsely claim the FDA withdraw a demand for a new Ampligen trial which Hemispherx was unprepared and/or unable to meet; (c) claim that its studies demonstrated effectiveness of Ampligen where the studies were rife with methodological errors and Hemispherx failed to apply valid statistical analysis; (d) falsely suggest that Hemispherx's analytic approach had been externally validated; and (e) claim that statutory changes lowered its burden as a sponsor and reduced the timetable for approval, when they did no such thing in fact. Collectively, it is reasonable to think these statements would make an attentive investor far more sanguine about the prospects of Ampligen approval than was merited by the reality of the situation. Given that Ampligen was Hemispherx's flagship drug, such that FDA approval of Ampligen was an essential part of Hemispherx's value proposition as a company, I have little doubt that an attentive investor would find those statements and misstatements material.

The conclusion of materiality is further supported by—as instructed by the Third Circuit—looking to the movement of Hemispherx stock when the alleged misrepresentations were revealed. *See In re Burlington Coat Factory Securities Litigation*, 114 F.3d 1410 (3d Cir. 1997);*Oran v. Stafford*, 226 F.3d 275 (3d Cir. 2000). Here, when defendants' various allegedly misleading statements were contradicted by the FDA at the end of the class period, the price of

Hemispherx stock plummeted. This drop subsequent to disclosure strongly suggests that the withheld and/or misrepresented information was material information to investors. *See Oran*, 226 F.3d at 282.

c. Defendants' objections

While the defendants raise a series of additional objections to the complaint, these are not sufficient to defeat the claim.

First, the motion contends "the amended complaint does not adequately allege any misleading omissions regarding the PLoS One article." The basis for this contention is that PLoS One's publication fees and peer review process were public. The source for this allegation, however, is not in the complaint. Rather, it is from defendants' Exhibit 38, which is a non-official document that is not referred to or relied upon by the complaint, and whose authenticity is entirely unknown to the court. In any event, the alleged problems regarding the PLoS One article go beyond nondisclosure of PLoS One's publication fees and the nature of its peer review. Even if it were true that PLoS One's fees and peer review process were widely known, that would not generally defeat plaintiffs' claims related to the PLoS One article, which is alleged to be the source of substantive misrepresentations about what may validly be concluded about Ampligen from AMP 516.

Second, the motion contends Pambianchi's statements at the September 11, 2012 investor presentation are immaterial because of the contents of Pambianchi's presentation slides. Pambianchi's slides, located at defendants' Exhibit 37, are not referred to or relied upon by the complaint, and their authenticity is entirely unknown to the court. Moreover, irrespective of the slides' contents, the slides do not speak to whether Pambianchi made material misstatements in his oral presentation.

Third, the motion contends "Hemispherx's statements regarding the possibility of accelerated approval under FDASIA were not false," because the previous denials of fast-track status for Ampligen did not make it unreasonable for Hemispherx to "belie[ve] that it could rely on FDASIA, which the Agency had yet to interpret." This misstates plaintiff's argument as I understand it, which is that (a) insofar as the PDUFA updates provide new paths for fast-track approval, Ampligen was categorically ineligible for these new pathways, and (b) Hemispherx suggested the updates to the PDUFA process lowered the quantum of evidence necessary for Ampligen approval when, in fact, it did not. To the extent the parties dispute how the FDASIA statute may be reasonably interpreted, there is insufficient information before me to evaluate that dispute at this time.

Fourth, regarding those of the defendants' allegedly misleading sentences which were prefaced with the words "thinks" or "believes," the motion contends these statements are (a) forward-looking statements protected by a safe harbor provision of the PSLRA; (b) non-actionable statements of belief or optimism; (c) irrelevant statements of optimism. Because the defendants are alleged to have made additional material misrepresentations, it would not defeat the claim were these particular statements inactionable. Nevertheless, defendants' points here are not persuasive.

As to the PSLRA safe harbor, defendants argue the referenced statements "qualify as forward-looking statements in that they include words of futurity or belief." Forward-looking statements refer to a company's own future business plans and performance metrics, and they do not apply to characterizations of past events or current conditions. *Avaya*, 564 F.3d at 255. Here, the company's representations did not relate to its plans, but rather related to scientific findings and/or its beliefs about the FDA approval process, including key takeaways from the June 8

meeting after the meeting had occurred. Meanwhile, it cannot be that the mere inclusion of "words of futurity or belief" brings otherwise non-forward-looking statements within the PSLRA safe harbor. *See, e.g.*, *In re Immucor, Inc. Sec. Litig.*, 2011 WL 2619092, at *3 (N.D. Ga. June 30, 2011) ("[P]refacing otherwise non-forward-looking statements with the word 'believes' does not bring the statements within the PSLRA safe harbor."). In any event, the safe harbor provision does not apply to statements made with actual knowledge of falsity, *Avaya*, 564 F.3d at 254, which remains a distinct possibility in this case.

Next, the defendants contend these sentences were nonetheless inactionable statements of belief or optimism because Hemispherx never made guarantees or assurances regarding the likelihood the resubmitted Ampligen application would succeed. This is irrelevant to whether Hemispherx systemically misled investors about the key components of the Ampligen NDA and the nature of FDA feedback while presenting predictions about FDA approval of Ampligen that it should have known were unreasonable under the circumstances.

Finally, as to the defendants' contentions about immaterial puffery, it is true that "vague and general statements of optimism constitute no more than puffery and are understood by reasonable investors as such." *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 538 (3d Cir. 1999). However, the defendants are alleged to have made specific statements about the component pieces of the Ampligen NDA resubmission, the FDA's feedback to that point about those pieces, and specific reasons to predict approval. These statements were neither vague nor general, and, regardless, the huge drop in Ampligen stock price subsequent to the publication of the FDA's briefing package and the Advisory Committee's decision belies any suggestion that investors found the defendants' statements immaterial. *See Oran v. Stafford*, 226 F.3d at 282.

In short, the plaintiffs adequately pled misstatements and/or omissions of material fact.

B. Scienter

The defendants next contend the complaint does not plead sufficient facts to give rise to a strong inference of scienter as the PSLRA requires. *See Tellabs, Inc.*, 551 U.S. at 323. In response, the plaintiffs point to, among other things, the defendants' knowledge of and/or access to facts contradicting their materially deficient public statements, the defendants' possible motivations in knowingly making misrepresentations about the Ampligen NDA, and a lack of competing inferences emerging from the complaint.

In the context of a claim for securities fraud, a plaintiff may establish scienter by "setting forth facts that constitute circumstantial evidence of either reckless or conscious behavior." *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 534-35 (3d Cir. 1999); *Tellabs*, 551 U.S. at 319 n.3 ("Every Court of Appeals that has considered the issue has held that a plaintiff may meet the scienter requirement [of an action under Rule 10b-5] by showing that the defendant acted intentionally or recklessly."). While allegations relating to motive and opportunity may not independently support a finding of scienter, such considerations may amplify an inference of scienter as part of the holistic information available to the court. See *Avaya*, 564 F.3d at 276-79.

Here, the plaintiffs' allegations of misleading material statements are accompanied by substantial evidence suggesting the defendants knew or should have known of those statements' misleading nature, if in fact they were misleading. First, statements characterizing the feedback Hemispherx received from the FDA at the June 8 meeting imply that speakers knew the entirety of the FDA's feedback, including its concurrent warning that it would be unusual for a resubmitted NDA to succeed based on reanalysis of previously submitted data. Second, statements that the FDA withdrew its request for an additional study appear to have been outright false according to the complaint, without any reason for speakers to believe a basis in truth.

Third, as to statements lauding the results of the Ampligen trials, Hemispherx, Carter, and Strayer are all alleged to have been in position to know of departures from protocol, statistical manipulation, and the like. Fourth, regarding statements misrepresenting the level of external review, Hemispherx, Carter, and Strayer would have known of PLoS One's self-publish model because they oversaw publication in PLoS One and moreover they would have known of the departures from protocol that rendered FDA approval of protocol moot. Fifth, regarding statements representing the relevance of the PDUFA statutory updates to the Ampligen application, to the extent these statements were categorically false and there was no basis for the asserted belief, there is, at a minimum, a cogent inference of recklessness to the truth. Even as to Hemispherx's confident predictions about the outcome of its Ampligen resubmission, "[w]hen the FDA tells a company about problems with a product, and the company nonetheless continues to make confident predictions about a product, courts have inferred scienter and falsity." *In re MannKind Sec. Actions*, 835 F. Supp. 2d 797, 811 (C.D. Cal. 2011) (internal quotation omitted).

Furthermore, the allegations in the complaint suggest that, at least as to Hemispherx and Carter, the defendants possessed ample motive and opportunity to commit the fraud in question. *See Avaya*, 564 F.3d at 276-79. The change of control bonus provision gave Carter personal incentives relating to a stock sale in a way that departs from executives' typical compensation incentives. *Cf. id.* at 278-279 ("[M]otives that are generally possessed by most corporate directors and officers do not suffice [in demonstrating motive for purposes of scienter].). Meanwhile, Hemispherx was allegedly sufficiently short on cash at the time of the alleged misrepresentations that it could not afford to finance an additional clinical trial as the FDA had recommended, heightening its need for a lucrative stock sale. Finally, the statements in question were roughly concurrent with Hemispherx's signing an equity distribution agreement under

which over $20 million in proceeds were generated. *See Avaya*, 564 F.3d at 279 ("[I]f the stock sales were unusual in scope or timing, they may support an inference of scienter.") (quoting *Advanta*, 180 F.3d at 540). As to opportunity, because the FDA was bound by silence until the advisory committee meeting, the defendants had ample opportunity to make statements regarding the FDA without fear of contradiction. *See Advanta*, 180 F.3d at 534-35.

This all gives rise to an inference of scienter that is both cogent and compelling. *See Tellabs*, 551 U.S. at 323 (directing courts to ask "whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter"). Meanwhile, notwithstanding the defendants' contentions to the contrary, their allegedly misleading statements bear no hallmarks of good faith error. The defendants are sophisticated scientists running a regulated, publicly traded corporation; they are alleged to have misrepresented their regulator's feedback, misrepresented the legal context in which they operated, heralded scientific results which they knew to be the product of empirically faulty procedures and manipulated statistical analysis, and claimed a level of external review that simply did not exist. If the defendants have good faith explanations for these misstatements such as to make the inference of scienter less than strong, they do not emerge from the complaint.

At this early stage, the plaintiffs' allegations raise an inference of scienter that is stronger and more cogent than any explanation that would not include scienter. *See Tellabs*, 551 U.S. at 324 (inference of scienter must be "cogent and at least as compelling as any opposing inference one could draw from the facts alleged"). Accordingly, the requirements of the PSLRA as to scienter are satisfied. *See* 15 U.S.C. § 78u-4(b)(2).

B. § 20(a)

Defendants contend plaintiffs' § 20(a) claim must be dismissed because it is purely derivative of plaintiffs' § 10(b) and Rule 10b-5 claim. *See Avaya*, 564 F. 3d at 252. According to defendants' argument, to the extent plaintiffs have not stated a claim under Rule 10b-5, neither have they stated a claim under § 20(a). As I find plaintiffs indeed do state a claim under Rule 10b-5, plaintiffs' § 20(a) claim will not fall on that basis.

An appropriate order follows.